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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,326	04/03/2006	Yusuke Nakamura	082368-003000US	9667

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EXAMINER

GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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07/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,326	Applicant(s) NAKAMURA ET AL.	
	Examiner ANNE M. GUSSOW	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7,17-25,28,29,31,36,43-45,49 and 77 is/are pending in the application.
- 4a) Of the above claim(s) 5,17-25,28,29,31,43-45 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,36 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 1 has been amended.

Claims 5, 17-25, 28, 29, 31, 43-45, and 49 remain withdrawn.

2. Claims 1, 3, 4, 7, 36, and 77 are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 1, 3 4, 7, and 77 under 35 U.S.C. 112 first paragraph as lacking enablement is maintained.

Applicant's response filed March 28, 2008 has been carefully considered but is deemed not to be persuasive. The response states that the examiner appears concerned that the claims read on sequence fragments and partial complements. Applicants do not agree with the Examiner's position. However, in the interest of furthering prosecution, Applicants have amended claim 1 to set forth identity or hybridization over the full length of the sequence (see response page 6).

In response to this argument, the amendment of the claim to recite "the full-length of a complement" does not specifically address the concerns of the previous

office action. Hybridization, even under stringent conditions, does not require binding of each nucleotide in a sequence. Thus, a polynucleotide that hybridizes to the complement of SEQ ID No. 11 would not necessarily encode any polypeptide nor the CGX2 polypeptide as claimed. Additionally, the rejection addressed the structural and functional activity of the polypeptide – promoting cell proliferation and binding to MGC10334 and CENPC1 – as not being identified as related to a specific domain or region of the protein in relation to the 95% identity language in the claims. The structural and functional components of the rejection were not address in applicant's response.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

5. The rejection of claims 1, 3, 4, 7, and 77 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is maintained.

Applicant's response filed March 29, 2008 has been carefully considered but is deemed not to be persuasive. The response states that he examiner alleges that there is insufficient written description for fragments and partial complements. Applicants do not agree with the Examiner's position. However, in the interest of furthering prosecution, Applicants have amended claim 1 to set forth identity or hybridization over the full length of the sequence (see response page 7).

In response to this argument, this rejection specifically addressed the 95% identity language in claim 1b as related to the function of promoting cell proliferation and

binding to MGC10334 and CENPC1. Applicant has not identified the specific regions of the protein necessary for the claimed function and a protein having 95% identity to SEQ ID No. 12 could potentially have up to 46 mutated residues (5% of 911 residues).

Without the knowledge of the functional regions of the protein one of ordinary skill in the art would not be able to identify which proteins would be included in the broadly claimed genus of proteins and maintain the claimed function.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

6. The rejection of claims 1, 3, 4, 7, 36, and 77 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's response filed March 28, 2008 has been carefully considered but is deemed not to be persuasive. The response states that he examiner alleges that there is insufficient written description for fragments and partial complements. Applicants do not agree with the Examiner's position. However, in the interest of furthering prosecution, Applicants have amended claim 1 to set forth identity or hybridization over the full length of the sequence (see response page 7).

In response to this argument, the rejection was drawn to the polypeptide encoded by the polynucleotide that hybridizes to a complement of SEQ ID No. 11 in claim 1c. As set forth above, hybridization even under stringent conditions does not require binding of each nucleotide in a sequence. Thus, a polynucleotide that hybridizes to the complement of SEQ ID No. 11 would not necessarily encode any

polypeptide nor the CGX2 polypeptide as claimed even if the hybridization were to the full length of a complement.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is

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(571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

July 9, 2008

/David J Blanchard/
Primary Examiner, Art Unit 1643